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HEINZ et al.
S.N. 10/019,048
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REMARKS:

Claims 1-13 are currently pending. Claims 1-3 and 9 have been amended. Claim 13 is new.

Claim Objections

Claim 1 is objected to for allegedly containing an informality. The Examiner states that the term "this organism" is inconsistent with the terms in the other Claims. Claim 1 has been amended to recite "the organism" as per the Examiner's suggestion.

Applicants respectfully request withdrawal of this objection in light of the amended Claim contained herein. All of the Examiner's objections have been addressed and favorable action is solicited.

Claim Rejections under 35 USC § 101

Claim 9 is rejected for allegedly being directed to non-statutory subject matter. Applicants respectfully disagree but nonetheless, have amended the aforementioned Claim deleting the term "animal."

For at least the foregoing, Applicants respectfully request withdrawal of this rejection in light of the amended Claim contained herein. Favorable action is respectfully solicited.

Claim Rejections under 35 USC § 112 ¶2

Claims 1-10 are rejected for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Applicants respectfully disagree.

The Examiner states that the term "substantially reducing" is indefinite because, for example, one of ordinary skill would not know whether 10 or 51% constitutes a substantial reduction. Based on the disclosure in the instant Specification, the aforementioned term has clear and defined metes and bounds. The Examiner is directed to page 10, lines 44-47 of the instant Specification wherein the term "substantially reducing" is clearly defined: "Not substantially reduced is to be understood as meaning all enzymes which still have at least 10%, preferably 20%, especially 30%, of the enzymatic activity of the starting enzyme." Accordingly,

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one of ordinary skill in the art would have been able to determine the metes and bounds of the instant claim.

Additionally, in Claim 1, the Examiner states that the term "the enzymatic action of the polypeptides" allegedly lacks antecedent basis and that the term should be replaced with "the $\Delta 6$ -desaturase activity." Applicants respectfully disagree.

Applicants urge that the term "the enzymatic action of the polypeptides" clearly has antecedent basis and no changes in recited terms is necessary. Instant Claim 1 recites a process for preparing unsaturated fatty acids wherein at least one isolated nucleic acid sequence encoding a polypeptide has $\Delta 6$ -desaturase activity. Part c of Claim 1, wherein the term "the enzymatic action of the polypeptides" is recited obviously refers back to $\Delta 6$ -desaturase activity and one of ordinary skill in the art would clearly have no confusion when interpreting said terms.

Claims 2-3 are rejected for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Applicants respectfully disagree. Nonetheless, Applicants have amended Claims 2-3 to recite "isolated" nucleic acid.

Claim 4 is rejected for allegedly being vague and indefinite because the Examiner believes that it is unclear how an animal can be cultured. Applicants respectfully disagree.

Instant Claim 4 is written for one of ordinary skill in the art, and as such, a certain amount of skill and knowledge in the subject area is deemed to be known and understood by said skilled artisan. Every person of ordinary skill in the art well knows that a whole animal cannot be cultured in the sense of the instant invention but the same person with ordinary skill in the art would clearly understand what is meant by the term animal in Claim 4 – animal cells (*see e.g.* page 3, lines 34-37 of the instant Specification).

Claim 9 is rejected for the same reason as stated above for Claim 1, antecedent basis and a request for term replacement. Applicants' forward similar arguments as listed above for traversal of the instant rejection.

Applicants respectfully request withdrawal of this rejection in light of the amended Claims and arguments contained herein. All of the Examiner's objections have been addressed and favorable action is solicited.

Claim Rejections under 35 USC § 112 ¶1

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Claims 1-10 are rejected for allegedly failing to provide adequate written description for the instant inventions claimed. Applicants respectfully disagree.

The Examiner believes the instant disclosure fails to describe or identify the necessary structures within SEQ ID NO: 1 or any structural domains that are common to the derivatives of the sequence and sufficient for $\Delta 6$ -desaturase activity. Further, the Examiner asserts the instant Claims encompass any polypeptide of any length derived from SEQ ID NO: 1. Additionally, the Examiner dismissed Applicants previous arguments regarding algorithms and sequence isolation techniques as not addressing the issue of the prior 35 USC § 112 ¶1 rejections. In short, the Examiner believes the current invention, because of its lack of disclosure of embodiments, could not be envisaged by one of ordinary skill in the art and that too much experimentation would be needed by one of ordinary skill in the art to attempt to practice the instant invention.

Applicants urge that the Examiner is requiring conclusive evidence that one of ordinary skill in the art would be able to make and use the claimed invention using the application as a guide. MPEP 2164.05 states that the enablement evidence provided by the Applicant need not be conclusive but merely convincing to one skilled in the art. Applicants have provided sufficient information in the disclosure of the instant Specification for one of ordinary skill in the art to practice the instant invention. Therefore, the instant disclosure exceeds the aforementioned standards and the reasons are listed below.

Although Applicants believe Claim 1 is in condition for allowance, said Claim has been amended to recite 95% homology as calculated over the entire amino acid region (*See* instant Specification, page 7, line 21-22). As mentioned previously, the claimed activity is $\Delta 6$ -desaturase activity. Hence, the instant Claims do not read on any polypeptide of any length -- they read on polypeptides with at least 95% $\Delta 6$ -desaturase activity. Moreover, similar is true for the claimed sequences derived from SEQ ID NO: 1 and 2 according to the degeneracy of the genetic code. One of ordinary skill in the art would be able take the codon usage of the genetic code (readily available in even the most basic of Biology texts) and define each and every sequence derived from SEQ ID NO: 1 and 2 without any undue burden. It is simply a matter of matching amino acids to three letter codons.

For at least the reasons mentioned above, any skilled artisan would envisage the instant invention based on the instant disclosure and would need to perform undue experimentation to

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practice said instant invention. Accordingly, applicants respectfully request withdrawal of the rejection under 35 USC 112 ¶1. Favorable action is solicited.

Claim Rejections under 35 USC § 102

Claims 1-4 and 7-9 are rejected for allegedly being anticipated by Girke et al. (*Plant J.*, 1, 1998, 15: 39-48). Applicants respectfully disagree.

The cited art has a reference date of July, 1998, which the Examiner asserts is clarified, after contacting the publisher of said journal, as July 1, 1998. Even assuming the uncorroborated note contained therein, the instant Office Action is accurate, a July 1, 1998 "publication" date is incorrect. The date the relevant public (*i.e.* persons of ordinary skill in the art) can actually gain access to a publication is the date of publication for prior art purposes (*See In re Boyer*, 568 F.2d 1357 (CCPA) wherein it states "[t]he date on which the public actually gained access to the invention by means of the publication is the focus of the inquiry"). Thus, even though there is notation to a clarified date of July 1, 1998, the actual publication date for 102 (b) purposes is later. Scientific journals take, on average, at least two weeks from the date listed as the publication date until the document can be considered as having a printed publication date under 102 (b). The priority date of the instant application is less than one year after any date that the cited art would have been available to those of ordinary skill in the art and as such, Girke et al. does not anticipate the instant invention. Applicants therefore respectfully request withdrawal of the rejection under 35 USC § 102(b).

Claims rejected under 35 USC § 103

Claims 1-10 are rejected for allegedly being obvious in view of Girke et al. alone or in further view of Napier et al. Applicants respectfully disagree.

For similar reasons as listed above, Girke is not prior art and such, cannot be used as means to establish an obviousness rejection under 103. Moreover, since Girke et al. is not prior art, there would be no motivation to combine said cited art with Napier et al.

Accordingly, Applicants urge that the Examiner has not shown in the prior art some suggestion or motivation to make the claimed invention and a reasonable expectation for success in doing so. Favorable action is solicited.